

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION SERVICES STANDARD ADVISORY
COMMITTEE (CCSAC) MEETING**

Thursday, January 14, 2021

Zoom Meeting

APPROVED MINUTES

I. Call to Order

Chairperson Madder called the meeting to order at 7:30 a.m.

A. Members Present and participating remotely:

Ryan Madder, MD, Chairperson – Spectrum Health – Kent County
Kyle Sheiko, Vice-Chairperson – Michigan Outpatient Vascular Institute (MOVI) – Oakland County
Khaldoon Alaswad, MD, FACC, FSCAI – Henry Ford Health System (HFHS) – Wayne County
Omar E. Ali, MD – Detroit Medical Center (DMC) – Wayne County (joined late)
Edouard Daher, MD – Eastlake Cardiovascular, PC – Oakland County
William R. Felten, MD, MSHAL, FACC – Midland County
Carlos Fernandez, DO – Edward Sparrow Hospital – Ingham County (joined late)
Anita L. Hart, MD, FACP, SFHM – Blue Cross Blue Shield of Michigan – Oakland County
Srinivas Koneru, MD – K heart & Vascular Institute, PLLC – Macomb County
Susanne Mitchell – International Union, UAW – Macomb County
Mansoor A. Qureshi, MD – Trinity Health Michigan – Washtenaw County
Fadi A. Saab, MD – Advanced Cardiac & Vascular Centers for Amputation Prevention – Kent County
Frank Saltiel, MD, FACC, FSCAI – Ascension Michigan – Kalamazoo County
Steven B. H. Timmis, MD FACC – HeartPointe Cardiology (Formerly Northpointe Heart Center) – Oakland County (joined late)
Justin Trivax, MD – Beaumont Health – Oakland County
Douglas J. Wunderly, MD – Bronson Healthcare Group/Advanced Cardiac Healthcare, PLC – Kalamazoo County (joined late)

B. Members Absent:

William S. Porter, RN – UAW Retiree Medical Benefits Trust – Wayne County

- C. Michigan Department of Health and Human Services Staff present and participating remotely:

Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Mr. Sheiko, seconded by Dr. Timmis to accept the agenda as presented. Motion carried.

IV. Review of Draft Minutes – December 17, 2020

Motion by Mr. Sheiko, seconded by Dr. Trivax to accept the minutes as presented. Motion carried.

**V. Charge 7:
Review if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ASCs**

Andre Gauri, MD, Spectrum Health provided the subcommittee update. (Attachment A)

Discussion followed.

Motion by Chairperson Madder, seconded by Dr. Alaswad to accept the recommendations as presented and ask the subcommittee to look at minimum volume requirements for EP procedures in ASCs and to review the transfer times for rural areas and ASCs.

Discussion followed on the motion.

Roll call vote:

Wunderly – no response
Trivax – yes

Timmis – yes
Saltiel – yes
Saab – yes
Qureshi – yes
Mitchell – yes
Koneru – yes
Hart – yes
Fernandez – yes
Felten – yes
Daher – yes
Alaswad – yes
Ali – no response
Sheiko – yes
Madder – yes

Motion carried.

VI. Charges 4 and 5:

Charge 4 - Review if diagnostic cardiac catheterization services should be allowed to be performed in ambulatory surgical centers (ASCs)

Charge 5 - Determine if elective PCI procedures should be allowed to be performed in ASCs

Chairperson Madder and Dr. Daher provided the subcommittee update.
(Attachment B)

Discussion followed.

Motion by Chairperson Madder, seconded by Dr. Qureshi to accept the recommendation on volumes for initiation and maintenance for ASCs (same as hospitals w/o surgical backup): 750 procedural equivalents for a single lab, 1,000 to open up additional labs, 200 diagnostic cath sessions, and 150 sessions if you're in a rural location, scratch the primary PCI because they don't fit, and that the bar for ASCs is going to be 200.

Discussion followed on the motion.

Roll call vote:

Wunderly – no
Trivax – no
Timmis – no
Saltiel – yes
Saab – no
Qureshi – yes
Mitchell – yes

Koneru – yes
Hart – yes
Fernandez – yes
Felten – yes
Daher – no
Alaswad – yes
Ali – yes
Sheiko – no
Madder – yes

Motion carried.

VII. Next Steps

Updates from subcommittees.

VIII. Future Meeting Date

February 18, 2021

IX. Public Comment

1. Brett Jackson, Economic Alliance of Michigan (EAM)

X. Adjournment

Motion by Dr. Qureshi, seconded by Dr. Hart to adjourn the meeting at 9:29 a.m. Motion carried.

EP SAC Sub-Committee Recommendations: 1/14/2021

Dr Andre Gauri, Dr Shrin Hebsur, Dr Ilana Kutinsky, Dr. Anita Hart, Dr. Arfat Khan, Dr. Dipak Shah, Dr. Hakan Oral and Kyle Sheiko members.

- 1) Requirements for ASC to implant cardiac pacers and ICDs
 - a. < 20 minute transportation time to a tertiary care center
 - b. ASC must have transfer agreement and protocols with tertiary care center
 - c. ASC must have cardiac cath lab capabilities including pericardiocentesis equipment on site.
 - d. Transvenous single and dual chamber pacemakers implants , transvenous single and dual chamber ICD implants and all generator changes are allowed to be done in an ASC.
 - e. New insertion of Left Ventricular leads, HIS bundle, Left bundle leads, leadless pacers and subcutaneous ICD implants will be excluded from ASC.
 - f. A registry of acute outcomes of procedures in an ASC should be strongly considered.

- 2) Operator Requirements for device implant in ASC as follows:
 - a. At least 2 years of post fellowship experience as an implanter
 - b. Proof of prior experience of > 75 device implants as primary operator in the last 2 years post fellowship training
 - c. Cardiology Board Certification for PPM implants and EP Board Certification for ICD implants
 - d. Proof of active privileges for implanting devices, moderate sedation and admitting at the tertiary care hospital
 - e. Volume Requirements
 - i. >35 devices per year
 - ii. For ICD implanters, this must include >10 ICD implants per year
 - f. Proof of device follow up protocols in place.

	Current Volume Requirements	ASC Proposed Volume Requirements
Initiation Projection: 1. Overall Lab Volume 2. Adult Diagnostic 3. Primary PCI 4. Elective PCI	1. 750 PEs for single lab service; 1,000 PEs/Lab for multi-lab service (Rural is 500 PEs for single lab service) 2. 200 diagnostic cardiac cath sessions (300 PE); 150 diagnostic cardiac cath sessions (225 PEs) Rural 3. 36 Primary PCI sessions (97.2 PEs) 4. 200 PCI sessions (540 PEs)	Attachment B
Maintenance: 1. Overall Lab Volume 2. Adult Diagnostic 3. Primary PCI 4. Elective PCI	1. 750 PEs for single lab service; 1,000 PEs/Lab for multi-lab service (Rural is 500 PEs for single lab service) 2. 200 diagnostic cardiac cath sessions (300 PE); 150 diagnostic cardiac cath sessions (225 PEs) Rural 3. 36 Primary PCI sessions (97.2 PEs) 4. 200 PCI sessions (540 PEs)	
Expansion: 1. Overall Lab Volume 2. Adult Diagnostic 3. Primary PCI 4. Elective PCI	1. 1400 PEs/Lab 2. 200 diagnostic cardiac cath sessions (300 PEs); 3. N/A 4. N/A	
Relocation: 1. Overall Lab Volume 2. Adult Diagnostic 3. Primary PCI 4. Elective PCI	1. 750 PEs for single lab service; 1,000 PEs/Lab for multi-lab service (Rural is 500 PEs for single lab service) 2. 200 diagnostic cardiac cath sessions (300 PE); 150 diagnostic cardiac cath sessions (225 PEs) Rural 3. 36 Primary PCI sessions (97.2 PEs) 4. 200 PCI sessions (540 PEs)	
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Core Curriculum

SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory: (Endorsed by the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencionista; Affirmation of Value by the Canadian Association of Interventional Cardiology–Association Canadienne de Cardiologie d'intervention)*

Srihari S. Naidu,^{1*} MD, FSCAI, Herbert D. Aronow,² MD, FSCAI, Lyndon C. Box,³ MD, FSCAI, Peter L. Duffy,⁴ MD, FSCAI, Daniel M. Kolansky,⁵ MD, FSCAI, Joel M. Kupfer,⁶ MD, FSCAI, Faisal Latif,⁷ MD, FSCAI, Suresh R. Mulukutla,⁸ MD, FSCAI, Sunil V. Rao,⁹ MD, FSCAI, Rajesh V. Swaminathan,¹⁰ MD, FSCAI, and James C. Blankenship,¹¹ MD, FSCAI

INTRODUCTION

The SCAI Expert Consensus Statement: 2012 Best Practices in the Cardiac Catheterization Laboratory patient complexity demand optimal periprocedural communication, clinical management, documentation,

“Clinical competence guidelines state that in order to maintain proficiency while keeping complications at a low level, a minimum volume of 200 PCIs/year be achieved by all institutions.”

CORONARY ARTERY DISEASE

Clinical Decision Making

SCAI/ACC/AHA Expert Consensus Document: 2014
Update on Percutaneous Coronary Intervention Without
On-Site Surgical Backup

Gregory J. Dehmer,^{1*} MD, James C. Blankenship,² MD, Mehmet Cilingiroglu,³ MD,
James G. Dwyer,⁴ MD, Dmitriy N. Feldman,⁵ MD, Timothy J. Gardner,⁶ MD,
Cindy L. Grines,⁷ MD, and Mandeep Singh,⁸ MD, MPH

Key words: angioplasty; coronary artery bypass surgery; consensus

INTRODUCTION

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled “The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup” [1]. This document summarized the available data on the performance of

updates of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards and the ACCF/AHA/SCAI Clinical Competence in

¹Baylor Scott & White Health, Central Texas, Temple, TX. SCAI Writing Committee Member and Chair

²Geisinger Health System, Danville, PA. SCAI Writing Com-

“laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually.”

“This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually.”

“an institutional volume threshold of <200 PCIs annually appeared to be consistently associated with worse outcomes.”

“The existence of laboratories performing <200 PCIs annually that are not serving isolated or underserved populations should be questioned”

CLINICAL COMPETENCE STATEMENT

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

A Report of the American College of Cardiology Foundation/American Heart Association/
American College of Physicians Task Force on Clinical Competence and Training (Writing Committee
to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures)

Writing Committee Members

John G. Harold, MD, MACC, FAHA, *Chair**
Theodore A. Bass, MD, FACC, FSCAI,
Vice Chair†

Thomas M. Bashore, MD, FACC, FAHA,
FSCAI

Ralph G. Brindis, MD, MPH, MACC,
FSCAI*

John E. Brush, Jr, MD, FACC

James A. Burke, MD, PhD, FACC

Gregory J. Dehmer, MD, FACC, FAHA,
FSCAI†

Yuri A. Deychak, MD, FACC

Hani Jneid, MD, FACC, FAHA, FSCAI‡

James G. Jollis, MD, FACC‡

Joel S. Landzberg, MD, FACC

Glenn N. Levine, MD, FACC, FAHA

James B. McClurken, MD, FACC

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Issam D. Moussa, MD, FACC, FAHA, FSCAI†

J. Brent Muhlestein, MD, FACC

Richard M. Pomerantz, MD, FACC, FSCAI

Timothy A. Sanborn, MD, FACC, FAHA

Chittur A. Sivaram, MBBS, FACC

Christopher J. White, MD, FACC, FAHA,
FSCAI†

Eric S. Williams, MD, FACC*

*American College of Cardiology Foundation representative; †Society for
Cardiovascular Angiography and Interventions representative; ‡American
Heart Association representative

“An institutional volume threshold <200 PCIs/annually appears to be consistently associated with worse outcomes...Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year.”

“the writing committee recommends that an institution without onsite surgery with a volume fewer than 200 procedures annually, unless in a region underserved because of geography, should strongly consider whether or not it should continue to offer this service.”

“In 1990, Ryan et al. (65, p. 1473) recognized that operator skill and judgment are greatly influenced by personal experience and by the environment in which the operator practices.”

PROPOSAL FOR VOLUME REQUIREMENTS FOR CARDIAC CATHETERIZATION PROCEDURES IN AMBULATORY SURGICAL CENTERS



Framework and Justification for PCI in Ambulatory Surgical Centers

- 1) EASY randomized trial and multiple registries did not show any abnormal signal in SDD of patients post PCI in hospitals
- 2) Value Proposition for performing outpatient PCI in an ASC vs Hospital outpatient environment while dependent on consistent procedural efficacy and safety, offers improved efficiency of care, increase access to care, better patient satisfaction and reduced cost.
- 3) NCDR Registry from 1612 hospitals (n=667,424) reveal that major complications after PCI are rare, and exceedingly so for elective PCI. Cautious case selection based on patient and lesion characteristics can further reduce the risk of complication in the ASC setting

SCAI Statement Position May 8, 2020

Premise of Ambulatory Surgical Centers

- 1) ASC has to be approved by an accredited body ([The American Association for Accreditation of Ambulatory Surgery Facilities](#), [The Accreditation Association for Ambulatory Health Care](#), [Healthcare Facilities Accreditation Program](#), etc)
- 2) Perform low risk procedures (excluding STEMI, NSTEMI, ACS ~about 50-60% of cases currently performed in cath lab in the US)
- 3) Careful selection of patients and lesions will be critical to performing these procedures safely

Premise of ASC- Selection of Patients (Exclusion)

- 1) Decompensated CHF
- 2) Recent TIA
- 3) EF <30%
- 4) CRI (GFR < 45)
- 5) Anemia (Hgb <9)
- 6) Significant PAD limiting femoral or radial access
- 7) Severe pulmonary HTN
- 8) Any hemodynamic instability
- 9) Severe AS
- 10) Severe contrast allergy
- 11) Operator judgement

SCAI Statement Position May 8, 2020

Premise of ASC- Selection of Lesions (Exclusion)

- 1) Unprotected LM or 3 VD
- 2) Bifurcation lesions with significant side branch involvement
- 3) Severe calcification
- 4) Excessive angulated segment or proximal tortuosity
- 5) CTO
- 6) Thrombus in target vessel
- 7) Last remaining conduit
- 8) Upfront need for MCS
- 9) Operator judgement

SCAI Statement Position May 8, 2020

Premise of Ambulatory Surgical Centers

- 1) On going Quality Control
- 2) ASC PCI performance checklists
 - a) Prescheduling assessment
 - b) Morning of procedure assessment
 - c) Post PCI assessment
 - d) Predischarge assessment
 - e) 30 days f/u phone call assessment (proposed)
 - f) Transfer agreement with the hospital (proposed)

Premise of Ambulatory Surgical Centers (summary)

- 1) Cath labs in ASC will be performing significantly less complex cases compared with in hospital cath lab without surgical back up
- 2) Procedures will be performed by seasoned interventionalists with significant experience and not recently graduating fellows
- 3) BMC2 report 2nd quarter data shows us that 1% rate of CABG among 4611 patients
- 4) Standards for ASC should be comparable to standards set for hospitals w/o surgical back up

	Collaborative		
	n	Denom	Pct.
Coronary Perforation	33	4,768	0.7%
Tamponade	7	4,768	0.1%
Stroke	2	4,768	0.0%
Cardiogenic Shock	42	4,768	0.9%
Acute Closure	18	4,768	0.4%
No Reflow	46	4,768	1.0%
Side Branch Occlusion	25	4,768	0.5%

Justification

- 1) Procedures done in ASC's are going to be much less complex than one done in cath labs in hospitals w/o surgical back up
- 2) Requiring higher numbers of procedures to be done may translate into pressuring operators to perform PCI on less severe disease that they would not normally intervene on, just to meet the required numbers
- 3) Recommendation for 100 PCI/yr in ASC's instead of the 200 PCI/yr for cath labs in hospitals w/o surgical back is because patients that would be eligible to be performed in an ASC's are expected to be about 20-30% of the number of patients that are usually done at the hospital in the most ambitious estimate (We have to exclude ACS, STEMI, NSTEMI and complex cases)

Proposed Volume Requirements for ASC (Comparison with cath lab in hospitals w/o surgical back up)

Cath labs in hospitals w/o surgical back up

- 1) Overall lab volume: 750 PE for single lab, 1000 PE/lab for multi lab
- 2) Adult Diagnostic: 300 PE
- 3) Primary PCI: 36 PCI
- 4) Elective PCI: 200 PCI

Cath labs in ASC

- 1) Overall lab volume: 300 (diagnostic cath + PCI = 570 PE). Same requirements for multiple labs
- 2) Adult Diagnostic: 200 diag cath (300 PE)
- ~~3) Primary PCI: 36 PCI~~
- 4) Elective PCI: 100 PCI (270 PE)

Remove PE and Use Number of Procedures only to simplify things and avoid confusion

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